

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
In Re Application of

Woodward et al

Serial No: 08/876,937

Filed: June 16, 1997

For: NON-ACIDIC CYCLOPENTANE
HEPTANOIC ACID, 2-CYCLOALKYL
OR ARYLALKYL DERIVATIVES AS
THERAPEUTIC AGENTS

Box Amendment-Fee
Commissioner of Patents
Washington, D.C. 20231

Group Art Unit: 1621

Examiner: P. O'Sullivan

PATENT

#21

12/8/00
Jmiller

DECLARATION UNDER 37 CFR 1.131

Dear Sir:

The Declarant hereby declares as follows:

THAT, he is currently employed by Allergan, Inc. in the Department of Biological Sciences, Pharmaceutical Research & Development;

THAT, he has been employed at Allergan since 1982;

THAT, his research is in the field of glaucoma, in particular the effect of prostaglandin analogues on lowering intraocular pressure, among other fields;

THAT, he obtained a Ph.D. degree (Pharmacology) from CNAAP, Leicester School of Pharmacy 1980;

THAT, he obtained a B.S. (Pharmacology) in 1975;

THAT, he is named as an inventor in the above-identified patent application;

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THAT, he directed and supervised the following experiments, in the United States of America, prior to August 3, 1993, the filing date of U.S. Patent Number 5,510,383 to Bishop;

THAT, as described in Example 6, of U.S. Patent Number 5,352,708, i.e. the grand parent application of the present application, the effectiveness of AGN 192185 in lowering intraocular pressure (IOP) in dogs was measured;

THAT, AGN 192185 is the 1-CONH₂ analogue of fluprostenol;

THAT, as shown in Exhibit A, which is a true copy of page 85 of his Notebook (with only the dates blocked out) and is attached hereto and made a part hereof, a 0.1% solution of AGN 192185 in a vehicle was prepared and designated as 185B;

THAT, as shown in Exhibit B, which is a true copy of page 86 of his Notebook (with only the dates blocked out) and is attached hereto and made a part hereof, 185B was topically applied to one eye of eight dogs and the lowering of IOP in that eye over 24 hours was measured;

THAT, in Dog Numbers KHD2, KID2, AC2 and KLC2 the IOP in the eye that received 185B was lowered;

THAT, as shown in a graph format in Exhibit C, which is a true copy of page 20 of his Notebook (with only the dates blocked out) and is attached hereto and made a part thereof, 0.01% fluprostenol when tested as described in Example 6 of U.S. Patent Number 5,352,708 also shows a lowering of the IOP in dogs;

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THAT, as shown in a graph format in Exhibit D, which is a true copy of page 15 of his Notebook (with only the dates blocked out) and is attached hereto and made a part thereof, 0.1% fluprostenol when tested as described in Example 6 of U.S. Patent Number 5,352,708 also shows a lowering of IOP in dogs;

THAT, the results reported in Exhibits A through D clearly demonstrate that topical administration of fluprostenol and analogues thereof lower IOP;

The undersigned declares further that all statements made herein of his own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment or both under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Respectfully,

Nov 20, 2000
Date


David F. Woodward